III. REMARKS

Claim Status

Claims 1-4 are under consideration in this application. Claims 5-13 remain held withdrawn from consideration as being drawn to non-elected subject matter 37 CFR 1.142(b). New claims 14-16 have been added.

Election/Restriction

The restriction requirement is deemed sound and proper and is made FINAL.

Claim Rejections - 35 USC 102 and 103

The rejections under 35 USC 102 and 103 stand withdrawn in view of applicants' arguments in the instant response.

Claim Rejections - 35 USC 112

Claims 1-4 stand rejected under 35 U. S. C. 112, first paragraph, as failing to comply with the written description requirement because of the lack of description as to whether the instant hydrates are maintained upon storage.

The examiner bases this rejection on four distinct grounds:

1. Stability During Storage - lack of information regarding stability of the claimed compounds in storage.

2. Stability During Processing - lack of information regarding stability of the claimed compounds during further processing into pharmaceutical compositions.

3. X-ray Diffraction Patterns or Infrared Spectrum Data – failure to disclose X-ray diffraction patterns or infrared spectrum data.

4. Production and Isolation - lack of information regarding production and isolation of the claimed compounds.

Applicant's traverse this ground for rejection and respond to each of the examiners arguments as follows:

1. Stability During Storage - the claims do not make any mention of the stability of the claimed crystals. If the compounds themselves do not instantly degrade, for which there is no suggestion either in the art or in the examiner's argument, then the claims properly describe the scope of the inventive entity, which are the described crystals. Applicant has stated in his specification that the hydrates are stable [page 7, line 22]

The examiner references Brittain at page 126 on this topic. However, there Brittain is discussing "the development process and dosage form performance." Here applicant is claiming a chemical composition, not a dosage form, and the vicissitudes of dosage form development are not relevant to claims directed to a chemical composition.

2. Stability During Processing - with respect to the first point applicants note that the presently claimed hydrates may be used directly for oxidation to yield the corresponding sulfinyl compounds, which are then used as an anti-ulcerative [page 7, line 20 et seq.]. Further, the present claims are not use claims and the techniques required to use the crystals [maintain their stability during processing] are not an appropriate inquiry with regard to the patentability of composition claims.

The examiner references Brittain at page 127 on this topic. However, there Brittain is discussing the dosage form development. Here applicant is claiming a chemical composition, not a dosage form.

3. X-ray Diffraction Patterns or Infrared Spectrum Data – applicant acknowledges that both techniques provide useful data regarding a composition. Applicant respectfully suggests however, that the provision of such data is not required to properly [in terms of the patent law] define a composition where such composition is clearly defined by its chemical structure and its constituents, as is done in claims 1-4.

The examiner cites *In re Fouche*, 169 USPQ 429 (CCPA 1971), MPEP 716.02(b) in this context. However, both this case and this section of MPEP appear to be directed to the

burden on applicant to demonstrate unobviousness and to rebut a prima facie case of obviousness made out by the examiner. Here, the issue is 35 USC 112 not 103.

4. Production and Isolation - the present application contains four examples that illustrate the preparation of the inventively claimed crystalline hydrates in detail, in particular mentioning the solvents, the amount of water, the temperature and the method for obtaining the crystals. A general statement of the production procedure additionally appears at page 6, lines 26 et seq. of the specification.

The examiner states that applicants have failed to show how each hydrate is isolated and states that the declaration of Lobermann, while interesting, if of little if any probative value because it is not commensurate in scope with the claims because applicants' claims are not limited to one compound.

Applicants believe that the disclosure of the isolation of a representative compound is sufficient under law and that the suggestion in the examiner's remarks, that more compounds – or that all the claimed compounds – are required is not required under 35 USC 112.

Applicant encloses a revised declaration by Dr. Lobermann which additionally includes under item "D." a reference to an XRD-spectrum of the prepared pymetazol hydrate. The spectrum as such is attached to the Declaration as figure 1.

As set forth in the declaration of Dr. Lobermann, it is evident that according to the present invention crystalline hydrates are indeed obtained. This was exemplified for the compound pyrmetazol according to example 3 of the present application.

Consequently, applicants respectfully suggest that the present application complies with the written description requirement.

For the reasons set forth above applicants also respectfully suggest that the present application complies with the enablement requirement of 35 USC 112.

The Commissioner is hereby authorized to charge payment for the RCE fee and a one month extension of time ($910) as well as any other fees associated with this communication or credit any over payment to Deposit Account No. 16-1350.

Respectfully submitted,

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16 November 2006
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I hereby certify that this correspondence is being transmitted electronically, on the date indicated below, addressed to the Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 16 November 2006 Signature:

Lisa Shimizu
Person Making Deposit